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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,553

08/05/2003

Eli Cohen

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4743

7590

07/09/2008

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EXAMINER

SHEN, BIN

ART UNIT

PAPER NUMBER

1657

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/634,553	<b>Applicant(s)</b> COHEN ET AL.	
	<b>Examiner</b> BIN SHEN	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28, 2008 has been entered.

### ***Status of the Claims***

Claims 28-42 are considered on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-33, 35-36, 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwaki et al. (1999).

Iwaki et al. teach an apparatus (a two chamber aggregometer, page 2764, right column, line 3) comprising: two chambers (read on as a first and second testing cell: see page 2764, right column, line 3), and a processor (read on as a recorder: see page 2764, right column, lines 7-9), wherein the first and second blood sample characteristic data are indicative of a clot (clot formation read as platelet aggregation, see page 2766, left column, line 5) rate of formation measurement (read on as bleeding time assay: see page 2764, 2<sup>nd</sup> full paragraph), wherein the first portion and the second portion comprises a platelet rich plasma-patient plasma mixture (page 2763, right column, 3<sup>rd</sup> paragraph), wherein each of the first and the second portion comprises an activator (read on as forskolin, page 2764, left column, 3<sup>rd</sup> paragraph, line 7).

Therefore, the cited reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cohen (WO01/96879A2), in view of Yamamoto and Pravinkumar et al. (British J of Anaesthesia 2003;90(5)676-685).

Cohen teaches an apparatus for monitoring heparin (abstract and page 9, line 5) comprising: means for testing a first blood sample a first blood sample characteristic in the presence of heparin; means for testing a second blood sample a second blood sample characteristic in the absence of heparin (page 10, lines 3-5); means for comparing the first and second blood sample characteristic to determine the effects of heparin, wherein the first blood sample characteristic comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement a clot rate of lysis measurement of the first blood sample and the second blood sample characteristic comprises at least one of a clot strength measurement, a clot elasticity measurement, a clot rate of formation measurement, a clot time to formation measurement a clot rate of lysis measurement of the second blood sample (page 7, lines 1-2, page 8, 2<sup>nd</sup> and 3<sup>rd</sup> full paragraph and page 9, 2<sup>nd</sup> paragraph), wherein the second blood sample characteristic represents a fibrin contribution to hemostasis (page 7, line 1, and page 11, 1<sup>st</sup> full paragraph), wherein the second blood sample comprises a blood sample without heparin (page 10, line 4), wherein the first blood sample comprises a first heparinized blood sample prepared with a first quantity of heparin and a second blood sample comprises a second heparinized blood sample prepared with a second quantity of heparin, different than the first quantity of heparin (page 10, lines 3-5), wherein each of the first blood sample and the second blood sample comprises a platelet rich plasma-patient

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plasma mixture, wherein each of the first blood sample and the second blood sample comprises patient whole blood (page 7, lines 20-22, and page 1, lines 14-16), wherein each of the first blood sample and second blood sample comprises an activator (page 11, 1<sup>st</sup> full paragraph). In the presence of heparin, the first blood sample characteristic will (inherently) represent a contribution to hemostasis of activated platelets in the presence of HiT II because heparin can induce HiT II (see Pravinkumar below).

Cohen does not teach determining heparin-induced thrombocytopenia II complex, the second blood sample comprises a blood sample prepared with a quantity of heparin sufficient to substantially completely suppress platelet activation.

Yamamoto teaches an apparatus (a platelet aggregometer) for determining heparin-induced thrombocytopenia II complex (abstract).

Pravinkumar teaches that heparin induces thrombocytopenia II which form a white clot (page 676, right column, 1<sup>st</sup> full paragraph and page 677, lines 20-23), and suggest that the induction is dose responsive (page 680, 1<sup>st</sup> full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the apparatus of Cohen to determine heparin-induced thrombocytopenia II complex (HiT II) because Yamamoto teaches that a platelet aggregometer can be use to determine heparin induces thrombocytopenia II (see above). One would have been motivated to make the modification because Cohen et al. specifically described the use of the apparatus to monitor heparin therapy and Yamamoto and Pravinkumar et al. teach that heparin induces thrombocytopenia II and it is imperative to discontinue all source of heparin before the laboratory confirmation of HiT (see Pravinkumar, page 683, beginning of Summary), and would reasonably have expected success in view of Yamamoto's teaching that a platelet aggregometer can be used to determine the presence of heparin-induced thrombocytopenia II complex and Pravinkumar's teaching that heparin induces thrombocytopenia II in a dose responsive manner, wherein the second blood sample can be prepared with a quantity of heparin sufficient to substantially completely suppress platelet activation.

Claims 31-36 are rejected as being unpatentable over the above cited references because a person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of select the proper concentrations of heparin to test the appropriate first and second

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blood samples since a person of ordinary skill has good reason to pursue the known options within his/her technical grasp with predictable result.

Claims 37, 41, 42 are rejected as being unpatentable over the above cited references because the technique for making multiple test cells/chambers or multi-testing cell hemostasis testing machine or multi-testing machine to improve a known apparatus/device was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive.

Applicant argues that Yamamoto does not suggest using an overwhelming dosage of heparin in a testing methodology to identify clot formation to determine HiT II.

It is the examiner's position that the present invention claims for an apparatus, the limitation is met if the apparatus (as taught by Iwaki) has all the components (two test cell/chambers and a processor), how the apparatus is used/the sample is prepared/for determining any conditions, etc., are just a few examples of intended use of the apparatus, thus an two-chamber aggregometer (as taught by Iwaki) can be used to determine many conditions including HiT.

### ***Conclusion***

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

*B Shen*

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/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657